UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

LAUREN BOSSETTI, *et al.*,

Plaintiffs,

v.

Case No. 1:22-cv-523
JUDGE DOUGLAS R. COLE

ALLERGAN SALES, LLC,

Defendant.

OPINION AND ORDER

Lauren Bossetti, Deborah DiMeglio, and Tara Guida all took the drug Lexapro while pregnant. All subsequently gave birth to a child with autism spectrum disorder. Each then sued Allergan Sales, LLC, who designed[1] and manufactures Lexapro. They assert a host of statutory and common-law claims under the laws of their respective states (Ohio, New Jersey, and Virginia). In support of these claims, Plaintiffs allege, among other theories, that Allergan defectively designed Lexapro in a way that caused their children's disorders.

Allergan now moves to dismiss but in a targeted fashion. The company asks the Court to (1) preclude Plaintiffs, on federal preemption grounds, from relying on a design defect theory to support their claims, (2) dismiss certain of Plaintiffs' common-law claims as abrogated by state statute, and (3) dismiss Plaintiffs' request for punitive damages. And Plaintiffs have acquiesced in part—they voluntarily

[1] Technically, Plaintiffs allege a predecessor company designed Lexapro. (Doc. 1, #3). No party disputes that Allergan may bear liability, though, as a successor in interest. For purposes of this Opinion, the Court will refer to Allergan as Lexapro's designer.

dismissed those common-law claims that Allergan claimed were abrogated. Thus, only the first and third requests above remain pending. For the reasons discussed below, the Court **GRANTS** Allergan's Motion to Dismiss (Doc. 5) on these issues.

BACKGROUND

Lexapro is an FDA-approved antidepressant and anti-anxiety drug.[2] (Compl., Doc. 1, #2–3). Allergan designed, labeled, markets, and sells Lexapro. (*Id.* at #3). Lauren Bossetti of Ohio, Deborah DiMeglio of New Jersey, and Tara Guida of Virginia all took Lexapro while pregnant. (*Id.* at #1–2). But when they gave birth, medical professionals diagnosed each Plaintiff's child with autism spectrum disorder.[3] (*Id.* at #16). Plaintiffs believe Lexapro caused their children's disorders.

Bossetti, DeMeglio, and Guida sued Allergan in a nine-count Complaint asserting common-law and statutory claims under Ohio, New Jersey, and Virginia law. (*Id.* at #14–27). As noted, Allergan then moved to dismiss in three limited ways. (Doc. 5). First, Allergan claims federal law preempted any theory of relief tied to an alleged design defect in Lexapro's formulation. (*Id.* at #47–52). Second, it says that state law abrogated certain of Plaintiffs' common-law claims (Counts I–V as to Bossetti, Counts I–III and V as to DeMeglio, and Count I as to Guida). (*Id.* at #52–

[2] When deciding a motion to dismiss for failure to state a claim, the Court assumes that the complaint's factual allegations are true. Thus, the Court largely relies on the facts in Plaintiffs' Complaint for this decision but with the caveat that these facts are not yet established and may never be. *Koren v. Neil*, No. 1:21-cv-9, 2022 WL 974340, at *1 (S.D. Ohio Mar. 31, 2022).

[3] The Complaint at one point alleges Plaintiffs themselves developed autism spectrum disorder from taking Lexapro. (Doc. 1, #15). But reading the Complaint as a whole, the Court believes this is a typo and that Plaintiffs rather meant their children developed this disorder.

55). Finally, Allergan argues that Plaintiffs cannot pursue punitive damages under any theory. (*Id.* at #55–57). Beyond that, though, Allergan did not seek to dismiss the Complaint outright.

Plaintiffs responded in two ways. First, they moved to sever and dismiss the common-law claims Allergan challenged. (Doc. 11). The Court granted that motion. (Not. Order 3/17/2023). As a result, Counts I–V as to Bossetti, Counts I–III and V as to DeMeglio, and Count I as to Guida are no longer part of this case.

As for the remaining claims, Plaintiffs labeled Allergan's preemption argument premature. Accordingly, Plaintiffs asked the Court to deny Allergan's Motion on that basis and allow Plaintiffs to take discovery in support of their design defect theory. (Resp., Doc. 10, #83–84). Plaintiffs did not respond, however, to Allergan's arguments directed at punitive damages.

All matters are now ripe.[4]

LEGAL STANDARD

To survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6), a "complaint must present sufficient facts to 'state a claim to relief that is plausible on its face.'" *Robbins v. New Cingular Wireless PCS, LLC*, 854 F.3d 315, 319 (6th Cir. 2017) (quoting *Bell*

[4] The Court earlier raised concerns that Plaintiffs had filed their Complaint in an improper venue, and the Court ordered the parties to explain why it should not sua sponte transfer the matter to a different venue under 28 U.S.C. §§ 1404, 1406(a). (Not. Order 4/26/2023). In a joint response, the parties notified this Court—for the first time—that they previously had litigated this matter in Illinois. (Doc. 15). In that case, the parties agreed that Plaintiffs would voluntarily dismiss and further agreed Plaintiffs may refile "in federal court in Ohio." (*Id.* at #135). However, Plaintiffs did not attach this agreement to their Complaint. For future reference, it is helpful when plaintiffs attach to their complaints any agreements that bear on a court's ability to hear a given dispute.

Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)). In making that determination, the Court "construe[s] the complaint in the light most favorable to the plaintiff." *Bassett v. Nat'l Collegiate Athletic Ass'n*, 528 F.3d 426, 430 (6th Cir. 2008) (quoting *Directv, Inc. v. Treesh*, 487 F.3d 471, 476 (6th Cir. 2007)) (internal quotation marks omitted).

LAW AND ANALYSIS

Allergan's Motion originally placed three issues before the Court. (Doc. 5). But as noted, Plaintiffs have already resolved one of them by dismissing those common-law claims that Allergan attacked. (Doc. 11; Not. Order 3/17/2023). So that leaves two questions. First, whether federal law preempts Plaintiffs' ability to rely on design defect theories to support their various claims. And second, whether Plaintiffs can pursue punitive damages under any theory. The Court addresses them in that order.

A. Federal Law Bars Plaintiffs' Pre-Approval Design Defect Theories.

Plaintiffs' Complaint contains a host of allegations aimed at Allergan's design, manufacture, labeling, and sale of Lexapro. Among these allegations, Plaintiffs say that Allergan defectively designed Lexapro in a dangerous manner. (Doc. 1, #1–2). And although only Bossetti brings a claim specifically labeled "Design Defect"—Count VI—all three Plaintiffs allege design defect theories as support for their various statutory and (remaining) common-law claims. (Doc. 1, #14–27). That is, Plaintiffs seek to prove their claims through, among other things, reference to Allergan's formulation and design of Lexapro. Allergan, on the other hand, argues that federal law preempts any design defect claim or theory of relief. Thus, Allergan says, the Court can rule, based on Plaintiffs' Complaint, that any portion of a claim

that relies on an alleged design defect is preempted and fails as a matter of law. (Doc. 5, #48–49; Doc. 14, #117). The Court agrees.

The United States Constitution makes federal law supreme. U.S. Const., Art. VI, cl. 2. Courts operationalize this principle using the rubric of preemption. Federal law can expressly or impliedly preempt state law. *Yates v. Ortho-McNeil-Janssen Pharms., Inc.*, 808 F.3d 281, 293 (6th Cir. 2015). Express preemption arises when Congress states an intent to displace state law in statute. *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008). Federal law impliedly preempts state law in at least two circumstances: "when Congress intends federal law to occupy the field, or when state law conflicts with a federal statute." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372–73 (2000) (cleaned up). Courts generally refer to the latter of these two as "conflict preemption." *See, e.g.*, *Mut. Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472, 479–80 (2013) ("[S]tate laws that conflict with federal law are without effect.") (citations and internal quotation marks omitted).

Conflict preemption can arise in one of two ways: (1) "when it is impossible for a private party to comply with both state and federal law," or (2) when the state law is "an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Yates*, 808 F.3d at 294 (cleaned up) (quoting *Crosby*, 530 U.S. at 372–73). Here, Allergan relies solely on impossibility preemption.

Impossibility preemption is a demanding and narrow defense. *Id.* First, the court opens with an assumption the state retains its "historic police powers … unless [a different result] was the clear and manifest purpose of Congress." *Id.* (quoting

Wyeth v. Levine, 555 U.S. 555, 573 (2009)). Second, the court identifies the actions state law would compel the defendant to take. *Id.* And third, the court asks whether the defendant cannot take those actions because federal law expressly forbids it. *Id.* If federal law does not expressly do so, the court ends by asking "whether the defendant has presented 'clear evidence' that [a federal agency] would have prohibited the defendant from taking the necessary steps under state law." *Id.* (citing *Levine*, 555 U.S. at 571). Along those lines, courts have held that "when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 623–24 (2011).

Start with the state law. Plaintiffs bring multiple claims under Ohio, New Jersey, and Virginia law. But at this stage, no party has articulated the elements of these claims. Rather, all concede that the three states would impose some state-law duty, whether by statute, common law, or both, on Allergan to design a reasonably safe drug when it intends to sell that drug to the public. And the parties concede those state-law duties would generally apply both before and after FDA approval. So for this discussion, the Court will assume that is the case.

Turn next to federal law—the Food, Drug, and Cosmetic Act (FDCA). Relevant here, that Act requires drug manufacturers to gain approval from the FDA before marketing a drug in interstate commerce. *Bartlett*, 570 U.S. at 476. A manufacturer receives that approval by submitting a new drug application, including data related

to the drug's safety and efficacy. *Id.* The FDA can approve the drug *only* if it finds the drug "safe for use" under "the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof" with the "probable therapeutic benefits [] outweigh[ing] its risk of harm." *Id.* (quoting 21 U.S.C. § 355(d) and *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 140 (2000)). Once the FDA approves a drug, a manufacturer cannot change the drug's "qualitative or quantitative formulation of the drug product" without prior approval from the FDA. *Id.* at 298 (quoting 21 C.F.R. § 314.70(b)(2)(i)).

"As a general matter, plaintiffs injured by brand-name prescription drugs retain state-law tort remedies against the manufacturer of those drugs, provided it is not impossible for the drug manufacturer to comply with both state and federal law." *Yates*, 808 F.3d at 294. For example, federal law will not preempt a plaintiff's state-law claim where a drug manufacturer can meet the state duty by acting on its own volition without permission from the FDA. *See PLIVA, Inc.*, 564 U.S. at 624. But federal law will preempt a claim where the state-imposed duty would require a drug manufacturer to unilaterally design or redesign a safer drug in a way that conflicts with a manufacturer's federal law obligations. *Yates*, 808 F.3d at 294. And, as discussed below, a state duty cannot require a drug manufacturer to simply stop selling an already FDA-approved drug to comply with that duty. *See Bartlett*, 570 U.S. at 488 ("Our pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability.").

In their response, Plaintiffs concede federal law likely preempts any state duties requiring changes to a drug's composition *following* FDA approval. (Doc. 10, #84). Plaintiffs are right to do so. Redesigning Lexapro's chemical composition following FDA approval would constitute a "major" change, 21 C.F.R. § 314.70(b)(2)(i), and Allergan cannot make such a change without FDA permission. *See Yates*, 808 F.3d at 298. So post-approval design-defect claims are clearly preempted.

But, Plaintiffs say, state-law duties can also attach *before* FDA approval. (*Id.*). And here, Plaintiffs claim Allergan designed Lexapro defectively from the start, thereby violating those state duties. (*Id.* at #86). In other words, Plaintiffs essentially view federal law as creating a floor for safety standards, allowing states to impose safety requirements going above that threshold. With that in mind, Plaintiffs argue that federal law would not have stopped Allergan from designing an even safer Lexapro in the first instance—before the FDA evaluated the drug. So Plaintiffs ask for discovery on their *pre*-approval design defect rationale to find evidence supporting that theory.

The Sixth Circuit, though, has already closed that road. In *Yates v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, the circuit addressed whether a plaintiff may recover for injuries relating to a defendant's design choices made before FDA approval. 808 F.3d at 298. The circuit said no, labeling any hypothetical pre-approval duty as "too attenuated":

> To imagine such a pre-approval duty exists, we would have to speculate that had defendants designed [the drug] differently, the FDA would have approved the alternate design. Next, we would have to assume that [plaintiff] would have selected this [drug for use]. Further yet, we would

> have to suppose that this alternate design would not have caused [plaintiff] to suffer [an injury]. This is several steps too far.

Id. at 298–99. Beyond that, the circuit also found that the Supreme Court decision in *Mutual Pharmaceuticals Co., Inc. v. Bartlett,* 570 U.S. (2013), had tacitly foreclosed the pre-approval theory. *See Yates*, 808 F.3d at 300. In *Bartlett*, the high Court rejected a "stop-selling" rationale as a proposed alternative path for a defendant to comply with a state-law duty, on the grounds that "[o]ur pre-emption cases presume that an actor … is not required to cease acting altogether in order to avoid liability." 570 U.S. at 488. According to *Yates*, that reasoning also prevented plaintiffs from relying on a pre-approval design-defect theory:

> In contending that defendants' pre-approval duty would have resulted in a [drug] with a different formulation, [plaintiff] essentially argues that defendants should never have sold the FDA-approved formulation of [the drug] in the first place. We reject this never-start selling rationale for the same reasons the Supreme Court in *Bartlett* rejected the stop-selling rationale.

808 F.3d at 300.

Yates is directly on point. Like the plaintiff in *Yates*, Plaintiffs argue Allergan had a state-law duty to design a safer Lexapro before seeking FDA approval. That is the very theory *Yates* rejected, meaning Plaintiffs cannot rely on it here.[5] *See, e.g.*, *Fleming v. Janssen Pharms., Inc.*, 186 F. Supp. 3d 826, 833 (W.D. Tenn. 2016).

Seeking to avoid that outcome, Plaintiffs point to *Yates*'s procedural posture. (Doc. 10, #85). There, the circuit reviewed an opinion granting summary judgment,

[5] The Court acknowledges some out-of-circuit courts have cast doubt on *Yates*. *See, e.g.*, *Holley v. Gilead Scis.*, 379 F. Supp. 3d 809 (N.D. Cal. 2019). But if Plaintiffs wish to challenge *Yates*, that is a matter they must take up with the Sixth Circuit.

meaning the parties had already developed the record. 808 F.3d at 286. And the *Yates* court chastised the plaintiff for failing to precisely explain "what a pre-approval claim would look like in her case." *Id.* at 300. Plaintiffs argue that here they have not fully benefited from discovery, nor have they had an opportunity to "precisely" explain the duty they claim Allergan violated. Thus, discovery is needed, they say, before the Court rules on Allergan's preemption defense. (Doc. 10, #85–86).

The Court disagrees. Sure, impossibility preemption is a demanding defense, and in some (perhaps many) cases facts matter to that defense. But the *Yates* panel stated that it could not "conceive of any coherent pre-approval duty that defendants would have owed to [the plaintiff] when it was developing" the drug at issue. *Yates*, 808 F.3d at 300. And *Yates* spoke in terms of law, not fact, when labeling the pre-approval rationale akin to the "stop selling" rationale that *Bartlett* rejected. Simply put, a state-law duty that would require a drug manufacturer to stop selling—or indeed never *start* selling—a drug that ultimately received FDA-approval collides with the FDCA as a matter of law.

Against that backdrop, discovery that is meant to prove Allergan could have designed Lexapro better from the start provides no help. Taking their allegations at face value, Plaintiffs claim that Allergan should have never sold Lexapro in its current formulation in Ohio, New Jersey, or Virginia—even after the FDA approved it. That is the same *legal* argument the Sixth Circuit found incompatible with federal law. Factual discovery cannot change that result. For that reason, dismissal on the

pleadings is proper. *See, e.g.*, *Brashear v. Pacira Pharms., Inc.*, No. 1:21-cv-700, 2023 WL 3075403, at *3 (S.D. Ohio Apr. 25, 2023); *Fleming*, 186 F. Supp. 3d at 833.

In a last-ditch effort, Plaintiffs point to *Wimbush v. Wyeth*, 619 F.3d 632 (6th Cir. 2010). There, a district court had held that state-law tort claims against drug manufacturers conflict with the FDA's general authority to regulate the safety and efficacy of prescription drugs. *Id.* at 641–42. The *Wimbush* panel reversed, holding that "as a general proposition, we can discern no physical impossibility between complying with a state law duty to exercise reasonable care in the process leading up to placing a drug on the market and complying with the federal government's process for approving drugs," and that "we are not persuaded that it is *always* impossible to comply with both state law duties and FDA regulations in the process leading up to FDA approval." *Id.* at 643 (emphasis added). But the ruling stood on narrow terms: "We hold merely that FDA approval does not automatically preempt state law tort claims for negligence." *Id.* at 646.

Plaintiffs emphasize that *Yates* concedes "*Wimbush* is still good law." *Yates*, 808 F.3d at 300. From this, they say dismissal on the pleadings is premature given *Winbush*'s conclusion that the FDA's purpose and approval process do "not automatically preempt state law." 619 F.3d at 646.

Again, the Court does not agree. *Wimbush* and *Yates* are admittedly in tension. And *Wimbush*, as the earlier published decision, controls. *See Wright v. Spaulding*, 939 F.3d 695, 700 (6th Cir. 2019) ("Like most circuits, this circuit follows the rule that the holding of a published panel opinion binds all later panels unless overruled or

abrogated en banc or by the Supreme Court."). But *Wimbush* explored whether "as a general proposition" a manufacturer can comply with both FDA and state-law duties in the pre-approval context, while *Yates* specifically targeted the viability of pre-approval design-defect claims. And the latter context is the one that matters here.

Putting a point on that distinction, *Wimbush* preceded the Supreme Court's 2013 decision in *Bartlett*. And, as noted, the *Yates* court expressly relied on *Bartlett*'s "stop selling" rationale when rejecting a proposed pre-approval design-defect duty. *See Yates,* 808 F.3d at 293 ("[W]e find that Yates's design defect claim is preempted under *Bartlett*."). Under the law of this circuit, then, *Bartlett* freed the *Yates* panel to rule contrary to the *Wimbush* panel, at least as to pre-approval design-defect claims. *See Wright*, 939 F.3d at 700. In short, *Yates* and *Bartlett* together close the door on Plaintiffs' pre-approval design defect theory, *Wimbush* notwithstanding.

Accordingly, the Court holds that Plaintiffs cannot advance claims against Allergan based on a design defect theory. The remaining question, then, is how to implement that decision here. After all, Plaintiffs label only one count "Design Defect"—Count VI. That said, other counts rely on a design defect theory, at least in part. And Sixth Circuit precedent makes clear the Court can dismiss a portion of count where appropriate without dismissing the entire count. *See, e.g.*, *O'Neill v. Louisville/Jefferson Cnty. Metro Gov't*, 662 F.3d 723, 735–36 (6th Cir. 2011). Accordingly, the Court dismisses Count VI in its entirety, and also dismisses any portion of any remaining count that asserts liability based on arguments that Allergan should have designed Lexapro differently—whether pre- or post-approval.

B. Plaintiffs Cannot Pursue Punitive Damages.

The Court moves next to punitive damages. In its Motion to Dismiss, Allergan argued Plaintiffs had not stated a plausible claim for punitive damages. (Doc. 5, #55). Plaintiffs elected not to respond to that argument. When plaintiffs fail to respond to an argument raised in a motion to dismiss, courts routinely find the plaintiffs have waived any arguments they could have made. *See, e.g.*, *Lloyd v. Pokorny*, No. 2:20-cv-2928, 2020 WL 4455547, at *9 (S.D. Ohio Aug. 3, 2020). The Court finds such waiver here.

Still, "[t]he law in this Circuit is not entirely clear whether a party's mere failure to respond to a dispositive motion constitutes a sufficient ground for granting the motion." *LaDrigue v. City of Bay City*, No. 1:19-cv-11196, 2022 WL 1205000, at *7 (E.D. Mich. Apr. 22, 2022). So the Court will briefly address whether Plaintiffs have plausibly alleged a demand for punitive damages.

Plaintiffs' Complaint seeks punitive damages under both Ohio and New Jersey law. (Doc. 1, #18–19, 21–27). Ohio law does not permit punitive damages against a manufacturer of a drug if that drug was "manufactured and labeled … in accordance with" FDA guidelines. *Monroe v. Novartis Pharms. Corp.*, 29 F. Supp. 3d 1115, 1129 (S.D. Ohio 2014) (quoting Ohio Rev. Code §§ 2307.80, 2307.80(C)(1)). Still, the Ohio statute provides a narrow exception where a plaintiff can show by a preponderance of the evidence that the manufacturer fraudulently withheld information from the FDA related to the plaintiff's alleged harm. *Id.* The same is true in New Jersey. N.J. Stat. Ann. § 2A:58C–5(c). Plaintiffs presumably seek to rely on those exceptions.

But the Supreme Court has held that federal law largely preempts such "state-law fraud-on-the-FDA claims." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348–49 (2001) (concluding that the "federal statutory scheme amply empowers the FDA to … investigate suspected fraud"). This includes both Ohio's and New Jersey's statutes. *Brashear*, 2023 WL 3075403, at *6–7; *McDarby v. Merck & Co., Inc.*, 949 A.2d 223, 276 (N.J. Super. Ct. App. Div. 2008). And following *Buckman*, the Sixth Circuit recognized that such a claim may only proceed if "some federal agency" has already acknowledged fraud against the FDA. *In re Aredia & Zometa Prods. Liab. Litig.*, 352 F. App'x 994, 995 (6th Cir. 2009).

In other words, Plaintiffs may receive punitive damages under Ohio or New Jersey law only if the FDA (or some other federal agency) has already discovered that Allergan made a fraudulent representation about Lexapro to the FDA. *See Monroe*, 29 F. Supp. 3d at 1130. Yet Plaintiffs have provided no allegations along those lines. At most, they say Allergan "deliberately concealed the causal relationship between in utero exposure to Lexapro … and neurodevelopmental delay." (Doc. 1, #27). But they do not allege that Allergan concealed that causal link from the FDA—let alone allege that some agency uncovered any such concealment. Accordingly, Plaintiffs have not alleged a plausible claim for punitive damages, and the Court dismisses any claim for them here.

CONCLUSION

For the reasons discussed, the Court **GRANTS** Allergan's Motion to Dismiss (Doc. 5). Accordingly, Plaintiffs may proceed on these claims: for Bossetti, Counts VII

and VIII; for DiMeglio, Counts IV and IX; and for Guida, Counts II, III, IV, and V. But in proving those claims, Plaintiffs may not pursue a theory of relief relating to an alleged design defect in Allergan's formulation of Lexapro. And Plaintiffs may not pursue punitive damages. Finally, as no Plaintiff currently proceeds under Counts I or VI, the Court dismisses those counts in their entirety. In its Answer, Allergan may respond to the Complaint's allegations as though the dismissed counts and theory had not been included in the Complaint.

SO ORDERED.

June 15, 2023
DATE

DOUGLAS R. COLE
UNITED STATES DISTRICT JUDGE